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PAPER

12/02/2008

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,662	04/27/2001	Eva Raschke	8325-0012	9004
20855 ROSBINS & PASTERNAK 1731 EMBARCADERO ROAD			EXAMINER KELLY, ROBERT M	
	SUITE 230 PALO ALTO, CA 94303		ART UNIT	PAPER NUMBER
			1633	
			MAIL DATE	DELIVERY MODE

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 09/844,662 RASCHKE ET AL. Office Action Summary Examiner Art Unit ROBERT M. KELLY 1633 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 19 September 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 57.68-71.91 and 96-102 is/are pending in the application. 4a) Of the above claim(s) 91 and 96-102 is/are withdrawn from consideration. Claim(s) is/are allowed. 6) Claim(s) 57 and 68-71 is/are rejected. 7) Claim(s) 57 and 68-71 is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner, Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some * c) ☐ None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/SB/08)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

51 Notice of Informal Patent Application

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 September 2008 has been entered.

Claims 57, 68-71, 91, 93, and 96 have been amended with the present response.

Claim 93 is cancelled

Claims 57, 68-71, 91, and 96-102 are presently pending.

Note: specification citations

The Examiner will refer to Applicant's specification in terms of the paragraph number of the Application Publication of this Application: Publication No. 2002/0064802, rather than page and line number of the present specification, whenever possible (i.e., the amendments that do not matter to the argument/rejection/objections proffered).

Election/Restrictions

Claims 91 and 96-102 remain withdrawn as being drawn to non-elected inventions, per the restriction requirement of 4/7/04, response to restriction requirement of 5/10/04, and Official Action of 11/14/06, as well as the prosecution history.

Hence, Claims 57 and 68-71 are presently considered.

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Claim Status, Cancelled Claims

In light of the cancellation of Claim 93, all rejections and/or objections to such claim is rendered moot, and thus, are withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 645 (CCPA 1962).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3,73(b).

As noted in the Advisory Action of 8/28/08, the rejections of Claims 57 and 68-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-44 of U.S. Patent No. 7.235.354, are withdrawn.

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As noted in the Advisory Action of 8/28/08, the rejections of Claims 57 and 68-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 7,220,719, are withdrawn

To wit, the Terminal Disclaimer of 8/11/08 has been accepted.

As noted in the Advisory Action of 8/28/08, the rejections of Claims 57 and 68-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21, 22, and 25-27 of U.S. Patent No. 7,217,509, are withdrawn.

To wit, the Terminal Disclaimer of 8/11/08 has been accepted.

As noted in the Advisory Action of 8/28/08, the rejections of Claims 57 and 68-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 7,177,766, are withdrawn.

To wit, the Terminal Disclaimer of 8/11/08 has been accepted.

As noted in the Advisory Action of 7/28/08, the rejections of Claims 57 and 68-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 7,163,824, are withdrawn.

Specifically, the terminal disclaimer of 7/22/08 has been accepted.

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As noted in the Advisory Action of 8/28/08, the rejections of Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 7,097,978 are withdrawn.

To wit, the Terminal Disclaimer of 8/11/08 has been accepted.

As noted in the Advisory Action of 8/28/08, the rejections of Claims 57 and 68-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 7.070.934, are withdrawn.

To wit, the Terminal Disclaimer of 8/11/08 has been accepted.

As noted in the Advisory Action of 8/28/08, the rejections of Claims 57 and 68-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 7,067,317, are withdrawn.

To wit, the Terminal Disclaimer of 8/11/08 has been accepted.

As noted in the Advisory Action of 8/28/08, the rejections of Claims 57 and 68-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 7,045,304, are withdrawn.

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As noted in the Advisory Action of 7/28/08, the rejections of Claims 57, 68, 70, and 71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 7,026,462, are withdrawn.

Specifically, Applicant's terminal disclaimer filed 7/9/08 has been accepted.

As noted in the Advisory Action of 8/28/08, the rejections of Claims 57 and 68-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 7,013,219, are withdrawn.

To wit, the Terminal Disclaimer of 8/11/08 has been accepted.

As noted in the Advisory Action of 8/28/08, the rejections of Claims 57 and 68-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-61 of U.S. Patent No. 7,001,768, are withdrawn.

To wit, the Terminal Disclaimer of 8/11/08 has been accepted.

As noted in the Advisory Action of 8/28/08, the rejections of Claims 57 and 68-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,989,269 are withdrawn.

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As noted in the Advisory Action of 8/28/08, the rejections of Claims 57 and 68-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-85 of U.S. Patent No. 6,979,539 are withdrawn.

To wit, the Terminal Disclaimer of 8/11/08 has been accepted.

As noted in the Advisory Action of 8/28/08, the rejections of Claims 57 and 68-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6,933,113 are withdrawn.

To wit, the Terminal Disclaimer of 8/11/08 has been accepted.

The rejection of Claims 57 and 68-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 6,919,204 are withdrawn.

To wit, the Terminal Disclaimer filed 9/19/08 has been accepted.

The rejection of Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-66 of U.S. Patent No. 6.824.978 are withdrawn.

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As noted in the Advisory Action of 8/28/08, the rejections of Claims 57 and 68-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,785,613 are withdrawn.

To wit, the Terminal Disclaimer of 8/11/08 has been accepted.

As noted in the Advisory Action of 8/28/08, the rejections of Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,780,590 are withdrawn.

To wit, the Terminal Disclaimer of 8/11/08 has been accepted.

As noted in the Advisory Action of 8/28/08, the rejections of Claims 57 and 68-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-53 of U.S. Patent No. 6,777,185 are withdrawn.

To wit, the Terminal Disclaimer of 8/11/08 has been accepted.

As noted in the Advisory Action of 8/28/08, the rejections of Claims 57 and 68-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,689,558 are withdrawn.

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As noted in the Advisory Action of 8/28/08, the rejections of Claims 57 and 68-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6.610.489 are withdrawn.

To wit, the Terminal Disclaimer of 8/11/08 has been accepted.

As noted in the Advisory Action of 8/28/08, the rejections of Claims 57 and 68-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 6,607,882 are withdrawn.

To wit, the Terminal Disclaimer filed 8/11/08 has been accepted.

As noted in the Advisory Action, the rejections of Claims 57 and 68-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,599,692 are withdrawn.

To wit, the Terminal Disclaimer of 8/11/08 has been accepted.

As noted in the Advisory Action of 8/28/08, the rejections of Claims 57 and 68-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,534,261 are withdrawn.

As noted in the Advisory Action of 8/28/08, the rejections of Claims 57 and 68-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6.511-808 are withdrawn.

To wit the Terminal Disclaimer of 8/11/08 has been accepted.

As noted in the Advisory Action of 8/28/08, the rejections of Claims 57 and 68-71 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,503,717 are withdrawn.

To wit the Terminal Disclaimer of 8/11/08 has been accepted.

As noted in the Advisory Action of 8/28/08, the rejections of Claims 57 and 68-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6.453,242 are withdrawn.

To wit, the Terminal Disclaimer filed 8/11/08 has been accepted.

Claim Rejections - 35 USC § 102 - co-invented patents

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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As noted in the Advisory Action of 7/28/08, the declaration of inventorship by Dr. Case, filed on 7/9/08, overcomes the 102(e) rejections against U.S. Patent Nos., and hence, they have been withdrawn in such Advisory Action.

In light of the amendments, the rejections of Claims 57 and 68-71 under 35 U.S.C. 102(e) as being anticipated by each of US Patent Nos.: 7,235,354; 7,177,766; 7,045,304; 6,989,269; 6,785,613; 6,780,590; 6,777,185; 6,599,692; 7,220,719; 7,163,824; 7,013,219; 6,979,539; 6,933,113; 6,824,978; 6,689,558; 6,607,882; 6,534,261; and 6,453,242, are withdrawn.

To wit, there is no teaching to arrive at a specific embodiment claimed presently, only obviousness would lead one to embodiments of three fingers, one being a non-natural helix, and further to being sensitive to DNAse I.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

In light of the amendments, the rejections of Claims 57, 68, 70, and 71 under 35

U.S.C. 102(b) as being anticipated by Shin, et al. (1999) Proceedings of the National Academy of Sciences, USA., 96: 2880-84, are withdrawn.

To wit, Shin's zinc fingers are not chimeric for fingers.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

In light of the amendments, the rejections of Claims 57, 68, and 69 under 35

U.S.C. 102(b) as being anticipated by Stacey, et al. (1999) The Plant Cell, 11: 349-63, are

To wit, Stacey's zinc fingers are not chimeric for the fingers.

New Objections

withdrawn

Claim Objections

Claims 57 and 68-71 are objected to because of the following informalities:

Claim 57 recites "a non-naturally occurring zinc finger domain comprising 3 or more zinc finger domains, wherein at least one of the zinc finger domains comprises a non-naturally occurring recognition helix". However, a zinc finger domain does not comprise 3 or more zinc finger domains, but the zinc finger domain of the zinc finger protein may comprise 3 or more zinc fingers. Applicant is required to correct the terminology used. However, this claim is not rejected for lack of clarity, because the Artisan would know what is being claimed.

Claims 68-71 are objected to for depending from an objected-to base claim(s).

Appropriate correction is required.

New Rejections

Claim Rejections - 35 USC § 112 - clarity

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 57 and 68-71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 57 recites "a non-naturally occurring zinc finger domain comprising 3 or more zinc finger domains, wherein at least one of the zinc finger domains comprises a non-naturally occurring recognition helix". It is not clear if Applicant is claiming the alpha helix of a zinc finger, or the helix which is recognized, i.e., the nucleic acid. Hence, the metes and bounds of what Applicant is claiming are not clear.

Claims 68-71 are rejected for depending from a rejected base claim.

Claim Rejections - 35 USC § 112 - new matter rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 57 and 68-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for being drawn to new matter. The claim(s) contains subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 57 and 68-71 are complexes in cells, in which a generic zinc finger comprising at least 3 fingers, one of which recognizes a generic non-naturally finger is bound to cellular chromatin in a region sensitive to digestion with DNAse I.

There is simply no implicit or explicit description in the original claims and/or specification to demonstrate that Applicant had considered such genera to be the invention.

While there is generic description of modified fingers, recognizing modified sequences, and the use of DNAse I digestion (it is noted again this is a non-limitation as the region is so broad as to encompass a whole chromosome), no Artisan could reasonably envision that Applicant interpreted such to be in the invention. The reliance on various portions of the claims and/or specification as originally-filed therefore, only provides support in the form of obviousness. However, obviousness does not supplant the need to disclose to the Artisan the invention in a form that demonstrates possession. Obviousness is not possession.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 57 and 68-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of US Patent Nos.: 7.235.354; 7.177.766; 7.045.304; 6.989.269; 6.785.613; 6.780.590;

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6,777,185; 6,599,692; 6,453,242, 7,220,719; 7,163,824; 7,013,219; 6,979,539; 6,933,113; 6,824,978; 6,689,558; 6,607,882; and 6,534,26 alone and/or in combination.

As is previously of record, the complexes are obvious. However, the newly addressed limitations of 3 zinc fingers, one of which is a non-naturally occuring finger, and a region sensitive to digestion with DNAse I are addressed below by way of example, using U.S. Patent No. 7.235.354.

With regard to the region, such regions are so very large as to encompass whole chromosomes. There is no way to determine how close to such a DNAseI sensitive site the binding site is required to be, and hence, because all chromosomes have DNAseI sensitive sites (which aren't even required to be "hypersensitive"), the limitation is essentially non-limiting. Moreover, as is of record, because these regions are determined as accessible regions, and accessible regions are those regions which bind the zinc finger, it is clear that this DNAse I sensitive site is non-limiting.

With regard to modified zinc fingers, the '354 patent suggests making mutations to the fingers to recognize distinct nucleic acid sequences (e.g., col. 3, paragraph 3).

Moreover, zinc fingers with more than two fingers are known to be functional (e.g., cols. 3-4, paragraph bridging).

Hence, it would be obvious to make 3 or more zinc-finger containing zinc finger proteins, and wherein at least one is mutated, given the Art, and bind it to a gene, as shown in the patent(s). The Artisan would do so in making modified zinc fingers for binding to genes to activate/repress them, as taught, and often required to be bound in the claims of the patent(s). The Artisan would reasonably expect success, as the patents teach such.

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Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to ROBERT M. KELLY whose telephone number is (571)272-

0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

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like assistance from a USPTO Customer Service Representative or access to the automated

information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert M Kelly/

Primary Examiner, Art Unit 1633